IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. FLAWLESS BEAUTY LLC, and RDG IMPORTS LLC, limited liability companies, and JACK H. GINDI, and SUSANA B. BOLECHE, individuals, Defendants.	)	Case No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act" or "FDCA"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Flawless Beauty LLC, and RDG Imports LLC, limited liability companies, and Jack H. Gindi, and Susana B. Boleche, individuals (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval under 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, 1345, and its inherent equitable authority.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Flawless Beauty LLC ("Flawless") is a New Jersey limited liability company. Flawless operates from 1750 Brielle Ave, Unit A4, Ocean Township, New Jersey and 1215 Main Street, Asbury Park, New Jersey (the "Flawless Facility"), within the jurisdiction of this Court. Customers are able to purchase Defendants' products, which are sold under various brand names, directly from www.flawlessbeautyandskin.com ("Flawless website"), a website operated by Defendants. Additionally, Customers are able to obtain information about, and in some cases purchase, Defendants' products from other websites and social media accounts owned by, controlled by, or related to Defendants, including, but not limited to: www.relumins.com; Defendants' Google+ page; Defendants' Facebook page; and Defendants' postings on eBay, Amazon, and other online marketplace websites (collectively, "Defendants' websites").

5. Defendant RDG Imports LLC ("RDG") is a New Jersey limited liability company. RDG is the importing arm of Defendants' enterprise. RDG operates from its principal place of business, 800 Fifth Avenue, Asbury Park, New Jersey (the "RDG Facility"), within the jurisdiction of this Court. RDG's address is the side entrance to the Flawless Facility, and the two companies are co-located.

6. Defendant Jack H. Gindi is Flawless' Director and 90-percent owner. He is the sole owner of RDG, and the most responsible individual for both Flawless and RDG. He provides day-to-day oversight, manages employees, and is responsible for purchasing, importing, receiving, selling, holding, and distributing all products to consumers.

7. Defendant Susana B. Boleche is Flawless' President and a 10-percent owner. She is also "the face of the company," as her image appears on the Flawless website, and her name is listed on Flawless' shipping labels.

8. Defendants regularly import drugs from various countries, including the Philippines, New Zealand, China, and Japan, and introduce finished drugs into interstate commerce for shipment outside New Jersey.

9. Defendants import, process, pack, label, hold, and/or distribute drugs in interstate commerce, including among others: Relumins Advanced Glutathione and New Relumins Advanced Glutathione 3500 mg; Tatiomax Glutathione Collagen Whitening; Laennec Human Placenta Whitening; Relumins Advanced Oral Whitening & Antiaging Stack; Authentic Relumins Advanced White Stem Cell Therapy All In One Day Lotion; Authentic Relumins Advance Whitening Facial Cream With TA Stem Cell & Placenta; Relumins Medicated Professional Acne & Dark Spot Fighting Set; Natural Pearl Whitening Lotion; Authentic Kustie Beauty Slimming Activated Hot Cream; Authentic Mosbeau Placenta White Clarifying Toner; Gluta PowerPeel Soap; Relumins Advance White-Whitening Deodorant Roll-On; and Sante Barley Fusion. A full list of Defendants' current drug products is included at Attachment 1.

10. Defendants sell their drugs in interstate commerce directly to consumers through the Flawless website and via telephone orders.

PUBLIC HEALTH RISKS ASSOCIATED WITH DEFENDANTS' DRUGS

11. Defendants' unapproved new and misbranded drugs present serious public health risks, particularly Defendants' purportedly sterile injectable skin whitening drugs. Intravenous and intramuscular administration of drugs creates many risks, including nerve or blood vessel damage, blood-borne infection, superficial skin infection, cellulitis, abscess formation, and toxic systemic reactions. Lay persons who purchase Defendants' injectable drugs do not have the specialized medical skills and training that such administration requires.

12. Defendants' other unapproved new and misbranded drugs pose additional health risks. For example, Defendants' sell several products that they state contain human placenta, including the Laennec Human Placenta Whitening vials and the Authentic Relumins Advance Whitening Facial Cream With TA Stem Cell & Placenta. Products containing placenta can harbor microbes that can cause serious infections, including hepatitis, HIV, and herpes, among others.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

13. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

14. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128.

15. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

21 U.S.C. § 321(m). Defendants' labeling includes all labels, labeling, promotional materials, and Defendants' websites as defined in Paragraph 4.

16. Defendants distribute nearly 500 different products. See Attachment 1. Over 90% of them are categorized according to their method of administration as follows: (a) lyophilized vials; (b) ampules; (c) capsules and tablets; (d) creams and lotions; (e) liquids; (f) hard soaps; (g) gels and deodorant; and (h) teas. The vast majority of Defendants' products contain virtually the same skin whitening claims, which render Defendants' products drugs under the Act because such claims demonstrate that Defendants' products are "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

17. Certain of Defendants' products also contain, in addition to the skin whitening claims, unsubstantiated therapeutic claims that also render Defendants' products drugs under the Act because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B). For example, Defendants make the following claims on their website:

a. Authentic Relumins Advanced Glutathione (lyophilized vial) "competitively inhibits melanin synthesis."

b. Relumins Advanced Glutathione 3500mg "also contributes to good liver function"

c. Laennec Human Placenta Whitening (ampule), which allegedly contains human placenta, "inhibits the synthesis and agglutination of melanin by interrupting the function of L-DOPA."

d. Relumins Advanced White Oral Whitening Formula Capsules – Whitens, repairs & rejuvenates skin with Rose Hips, "contributes to good liver function," "help[s]

to protect the lungs," and "[h]as been used clinically to treat degenerative brain & liver diseases including Parkinsons."

e. Relumins Advanced Oral Whitening & Anti-Aging Stack (capsule & tablet), which allegedly contains horse placenta, "[c]ontrol[s] cholesterol and high blood pressure" and is "used [to] clinically treat degenerative brain & liver diseases including Parkinsons [sic]."

f. Authentic Kustie Beauty Slimming Activated Hot Cream (cream & lotion) contains "powerful slimming and anti-cellulite ingredients."

g. Authentic Mosbeau Placenta White Clarifying Toner (liquid), which allegedly contains placental protein, allows the consumer to "[g]et whiter skin[.]"

h. Gluta PowerPeel Soap (hard soap) "[r]educes melanin synthesis [and] prevent freckles/sun spots."

i. Relumins Advance White-Whitening Deodorant Roll-On (gel & deodorant) "[w]hitens [d]ark [u]nderarms."

j. Sante Barley Fusion (tea) "[r]educe[s] inflammation" and "may protect against degenerative disease."

18. Under the Act, Defendants' products are not only drugs, but also "new" drugs. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must (1) have substantial evidence of safety and effectiveness as demonstrated through adequate and well-controlled clinical

studies; (2) the studies on which a claim of GRAS/E is based must be published in the scientific literature so that they are made generally available to the community of qualified experts; and (3) there must be a consensus of opinion among qualified experts, which is based on the published studies, that the drug is safe and effective for its labeled indications. If it is an over-the-counter ("OTC") drug, it must comply with a monograph established under Food and Drug Administration ("FDA") regulation. 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

19. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. § 355(a), (b), (i), and (j).

20. The introduction or delivery for introduction into interstate commerce of an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

21. Defendants' drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Moreover, Defendants' drugs do not conform to any OTC drug monograph.

22. FDA representatives searched agency records and determined that Defendants do not have any approved NDA, ANDA, or IND applications on file with the agency to date.

23. Defendants introduce unapproved new drugs, or cause them to be introduced, into interstate commerce, in violation of 21 U.S.C. § 331(d).

DEFENDANTS DISTRIBUTE MISBRANDED DRUGS

24. The introduction or delivery for introduction into interstate commerce of any misbranded drug violates the Act. 21 U.S.C. § 331(a).

25. Misbranding a drug that is held for sale after shipment in interstate commerce violates the Act. 21 U.S.C. § 331(k).

26. A drug is misbranded within the meaning of 21 U.S.C. § 352(a) if its labeling is false or misleading in any particular.

27. Some of Defendants' drugs are misbranded under 21 U.S.C. § 352(a) because their labeling suggests or implies FDA approval or endorsement. There is no such FDA approval in effect for any of these products. For example:

a. The labeling for the "Relumins Advanced Glutathione 3500mg" and the "Relumins Advanced Glutathione 3500 mg plus Booster" includes the phrases "FDA registered formula," "registered with the FDA to ensure the highest level of quality, purity, and safety," and "the only brand to be registered with the FDA;" there is no such FDA registration for these products;

b. The webpages for the "Relumins Advance Whitening Facial Cream with TA Stem Cell & Placenta – Intensive Repair & Sun Protection;" "Relumins Advance White Stem Cell Therapy All in One Day Lotion – Most Advanced Skin Whitening & Repair;" "Relumins Advance Whitening Soap with Intensive Skin Repair & Stem Cell Therapy;" "Relumins Advanced White Oral Whitening & Anti-Aging Stack" and "Relumins Advanced White Oral Whitening Formula Capsules – Whitens, repairs & rejuvenates skin with Rose Hips" products display images of various types of FDA export certificates, many of which are expired. The issuance of FDA export certificates or certificates of "free sale"

do not indicate FDA approval, as stated in the cover letter that accompanies such certificates, yet depicting the images of such certificates on the product webpages from which customers can purchase the products is misleading as it implies FDA endorsement of the products; and

c. The webpages for the "Relumins Medicated Professional Acne & Dark Spot Fighting Set;" "Relumins Medicated Professional Acne Clear Set with Acne Fighting Botanicals;" and "Relumins Medicated Professional Total Acne & Dark Spot Fighting Set for Hard to Whiten & Sun Damaged Skin" products claim that "Relumins Pro Acne Care formulas contain FDA approved acne medication . . . ." This claim is false or misleading because it suggests that the products are the subjects of FDA-approved applications when there are no such approvals.

28. A drug is also misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use, " as defined by 21 C.F.R. § 201.5(a) and it does not fall within a regulatory exception from that requirement. Under 21 C.F.R. § 201.5, "adequate directions for use" are defined as "directions under which the layman can use a drug safely and for the purpose for which it is intended." Because Defendants' products are unapproved new drugs, as described above, these drugs are not exempt from the requirement for adequate directions for use. 21 C.F.R. §§ 201.100(c)(2), 201.115.

27. Adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing. It would be impossible to write such directions for Defendants' drugs, because adequate directions for drug use, including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures, are necessarily premised on animal and clinical data derived from extensive,

scientifically controlled testing.

30. Defendants do not have any well-controlled clinical test data for their drugs. Consequently, adequate directions under which a layman can safely use these drugs cannot be written.

31. Some of Defendants' drugs are prescription drugs because of the purposes for which they are intended, including the cure and treatment of liver disease, Parkinson's disease, high cholesterol, and/or high blood pressure, or by their method of administration, namely injection. 21 U.S.C. § 353(b)(1)(A).

32. By definition, a prescription drug cannot contain adequate directions for lay use, see 21 U.S.C. § 353(b)(1)(A), and thus Defendants' prescription drug products are misbranded under 21 U.S.C. § 352(f)(1).

33. A prescription drug is also misbranded within the meaning of 21 U.S.C. § 353(b)(1) if it is dispensed without a prescription. Defendants' prescription drugs are dispensed without a prescription, causing them to be misbranded under 21 U.S.C. § 353(b)(1).

34. A prescription drug is further misbranded "if at any time prior to dispensing, the label of the drug fails to bear, at minimum, the symbol 'Rx only.'" 21 U.S.C. § 353(b)(4). Defendants' prescription drugs fail to bear the symbol "Rx only," causing their prescription drug products to be misbranded under 21 U.S.C. § 353(b)(4).

35. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce certain drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4).

36. Defendants violate 21 U.S.C. § 331(k) by causing certain drugs that defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), 353(b)(1), and 353(b)(4).

DEFENDANTS DISTRIBUTE AND HOLD MISBRANDED AND UNAPPROVED NEW DRUGS IN INTERSTATE COMMERCE

37. During inspections of the Flawless Facility in 2014 and 2015, FDA investigators identified records demonstrating that Defendants ship their misbranded and unapproved new drugs in interstate commerce to locations outside of New Jersey, including Texas, Florida, California, and Maryland. These shipments constitute the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. § 331(a) and (d).

38. In addition, during inspections of the Flawless Facility in 2014 and 2015, FDA investigators collected records demonstrating that Defendants import many of their drug products from other countries, such as the Philippians, New Zealand, China, and Japan. Since Defendants receive their products from outside of New Jersey and hold them for future sale, the interstate commerce element under 21 U.S.C. § 331(k) is satisfied.

DEFENDANTS' HISTORY OF FDCA VIOLATIONS

39. Before operating Flawless, Defendant Gindi operated a firm called Xceed College Advisors LLC ("Xceed") that was located at the same address as the Flawless Facility. Defendant Gindi changed Xceed's name to Flawless in 2012. On July 9 and 31, 2013, FDA representatives sent Flawless and Xceed letters informing them that several of their imported products, some of which were intended to whiten skin and/or be injected, were refused admission for reasons including, but not limited to, the fact that they appeared to be new drugs without an effective NDA, thereby violating 21 U.S.C. §§ 355(a) and 381(a)(3).

40. FDA investigators conducted an inspection of the Flawless Facility from March 24, 2014, through May 16, 2014. At the close of the inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("Form-483") to Defendant Gindi for Defendants' failure to establish a quality control unit or assure the identity, strength, quality, and purity of its finished drug products. Defendant Gindi also recalled six injectable products distributed by Flawless. During the closeout meeting held on May 16, 2014, FDA investigators discussed with Defendant Gindi Defendants' obligations under FDCA and its implementing regulations.

41. On September 4, 2014, the United States filed a Complaint for Forfeiture in Rem against all misbranded and unapproved new drugs located at the Flawless and RDG Facilities. See United States v. Undetermined Quantity of Relumins Advanced Glutathione Kits, 2:14-cv-05502-FSH, Docket No. 1 (D.N.J. Sept. 4, 2014). Pursuant to an arrest warrant in rem, Deputy U.S. Marshals seized over $10,000 of Defendants' misbranded and unapproved new drugs. Although Defendants were notified about this proceeding in accordance with the Federal Rules of Civil Procedure, they did not file a claim, and default judgment condemning the drugs and forfeiting them to the United States was entered against the condemned articles on February 17, 2015. See United States v. Undetermined Quantity of Relumins Advanced Glutathione Kits, 2:14-cv-05502-FSH, Docket No. 6 (D.N.J. Feb. 17, 2015). The articles were subsequently destroyed by the United States Marshals Service on or about April 14, 2015.

42. FDA also inspected the Flawless Facility from April 29, 2015, through May 26, 2015. During the inspection, Defendant Gindi stated he no longer imports, receives, holds, sells, or distributes any injectable products through the facility in Asbury Park, New Jersey. At the close of the inspection, FDA issued a Form-483 for Defendants' failure to establish a procedure for handling complaints and have a quality control unit. Investigators also held a close-out meeting

with Defendant Gindi, at which they reminded him of his obligations to comply with the Act and its implementing regulations.

43. Despite Defendant Gindi's statements to the contrary, Defendants continue to sell unapproved new and misbranded drugs, including injectable drugs.

44. Defendants' history of importing and distributing misbranded and unapproved new drugs and their unwillingness to comply with the Act supports an injunction under the Act. Based on their recent course of conduct, it is evident that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a), (d), and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a) and the Court's inherent equitable authority, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(a), 352(f)(1), 353(b)(1), and 353(b)(4); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(a), 352(f)(1), 353(b)(1), and 353(b)(4);

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a) and the Court's inherent equitable authority, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive notice of the Court's order, from importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, or distributing any articles of drug, unless and until Defendants' methods and controls used to import, receive, manufacture, prepare, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity the Act and its regulations, in a manner that has been found acceptable by FDA;

III. Order that FDA be authorized under this injunction to inspect Defendants' place(s) of business and all records relating to importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, and distributing any of Defendants' drug products to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be granted judgment for its costs herein and that the Court grant such other and further relief as it deems just and proper.

DATED this 12th day of September, 2017.

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

JOSHUA I. WILKENFELD
Acting Director, Consumer Protection Branch

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, NW
6th Floor, South
Washington, DC 20044

Of Counsel:

JEFFREY S. DAVIS
Acting General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

SONIA W. NATH
Associate Chief Counsel for Enforcement
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993